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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/521,534	08/31/2005	Peter Serno	Le A 35 683	8954

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Barbara A. Shimci
Director, Patents & Licensing
Bayer HealthCare LLC - Pharmaceuticals
555 White Plains Road, Third Floor
Tarrytown, NY 10591

EXAMINER	
SHEIKH, HUMERA N	

ART UNIT	PAPER NUMBER
1615	

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05/11/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/521,534	SERNO ET AL.	
	Examiner	Art Unit	
	Humera N. Sheikh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 January 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2, 4-6, 8-10 and 14-19* is/are pending in the application.

4a) Of the above claim(s) *6,8-10 and 16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 2, 4, 5, 14, 15 and 17-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Receipt of the Response to Non-Final Office Action, the Amendment and Applicant's Arguments/Remarks, all filed 01/06/10 is acknowledged.

Applicant has overcome the following rejection(s) by virtue of the amendment and/or persuasive remarks: (1) The 35 U.S.C. §112, first paragraph rejection of claims 1-5, 7 and 11-15 has been withdrawn; (2) The 35 U.S.C. §103(a) rejection of claims 1-5, 7 and 11-15 over Niewöhner *et al.* alone (USPN 6,362,178) and (3) Niewöhner *et al.* in view of Bischoff *et al.* (WO 01/19357) has been withdrawn.

Claims 1, 2, 4-6, 8-10 and 14-19 are pending in this action. Claims 1, 2, 4, 5, 8-10, 14 and 15 have been amended. New claims 17-19 have been added. Claims 3, 7 and 11-13 have been cancelled. Claims 6, 8-10 and 16 remain withdrawn. Claims 1, 2, 4, 5, 14, 15 and 17-19 have been examined in this action. Claims 1, 2, 4, 5, 14, 15 and 17-19 are rejected.

* * * * *

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 4, 5, 14, 15 and 17-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to

reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants claim a method for producing medicaments comprising vardenafil hydrochloride trihydrate in solid form; a coated tablet obtainable by the method and a method for the treatment and/or prophylaxis of sexual dysfunctions and erectile dysfunction. The process steps and written description are insufficient and have not been presented in such a way as to allow one of ordinary skill in the art to understand and practice the invention. For instance, the method of production of claim 1 and the scope of the claims is distinct from the examples presented in the specification. For instance, the examples demonstrate that the use of coating agents (i.e., hypromellose, macrogol) and disintegrants (i.e., microcrystalline cellulose, crospovidone) are needed as a critical part of the manufacturing process but the instant claims are not representative of the examples provided in the specification. No specific formulations have been set forth to allow one of ordinary skill to know how to carry out a method for producing medicaments comprising vardenafil hydrochloride trihydrate in solid form and a coated tablet which would yield from the stated method of production.

In particular, Applicants should identify the specific "excipients" used in the manufacturing process in terms of the coating agents (i.e., hypromellose, macrogol) and in terms of the disintegrants (i.e., microcrystalline cellulose, crospovidone) employed, in addition to any other required excipients used to formulate the coated tablet.

* * * * *

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 recites "wherein said step of coating is carried out before said treating step". This limitation renders the claim indefinite because it contradicts claim 1, which requires that the treating step occur prior to or before the coating step. For instance, claim 1 recites step (b) of "treating said tablet with a moistened gas", followed by step (c) of "coating said tablet". Thus, while claim 1 recites "treating" followed by "coating", claim 2 recites "coating" followed by "treating" and thus, renders the claim confusing as to which process step occurs first – "treating" or "coating"? Clarification is requested.

* * * * *

Response to Arguments

Applicant's arguments filed 01/06/10 have been fully considered and were found to be partially persuasive.

- **35 U.S.C. §112, first paragraph:**

Applicant argued, "The pending claims have been amended in accordance with the Examiner's suggestion at page 5 of the Action."

This argument has been considered and was found persuasive based on the amendment to the claims. Accordingly, the 35 U.S.C. §112, first paragraph rejection of claims 1-5, 7 and 11-15 has been withdrawn.

Applicant argued, "Claim 1 has been rewritten to recite specific procedures. Furthermore, contrary to the Examiner's assertion at page 6 of the Action, the examples

in the specification (i.e., Exs. 6 & 10) demonstrate that various kinds of excipients may be used in the manufacturing process."

This argument has been considered but was not found persuasive. While Applicant has amended to the claims to recite the specific procedures and use of the term "excipients" to better present their manufacturing process steps, it is suggested that Applicants further identify the specific "excipients" used in the manufacturing process in terms of the coating agents (i.e., hypromellose, macrogol) and in terms of the disintegrants (i.e., microcrystalline cellulose, crospovidone) employed, in addition to any other required excipients used to formulate the coated tablet. Applicant may present the specific excipients in a Markush grouping format.

This rejection has been maintained herein.

- **35 U.S.C. §103(a) over Niewöhner *et al.* alone (USPN 6,362,178) and Niewöhner in view of Bischoff *et al.* (WO 01/19357):**

Applicant argued, "Niewöhner does not disclose any specific conditions that could be used for making the hydrates from a pre-formed tablet and does not teach that a moistened gas might by employed in converting any compound into its hydrate form (i.e., trihydrate). Niewöhner does not teach a process or condition under which a high percentage (e.g., 90% or higher) of the vardenafil hydrochloride may be converted into the single form of the hydrates (trihydrate), rather than being converted into any other forms of the hydrates or mixtures of hydrates. Applicants have found that the claimed process is able to produce solid medicaments containing vardenafil hydrochloride trihydrate in a uniform and reproducible form."

These arguments have been considered and were deemed persuasive based on the amendment to the claims. Accordingly, the 35 U.S.C. §103(a) rejection of claims 1-5, 7 and 11-15 over Niewöhner *et al.* alone (USPN 6,362,178) has been withdrawn.

Applicant argued, "Bischoff does not teach or suggest any method for converting vardenafil hydrochloride contained in a pre-formed tablet, including the core, into any specific hydrate form, nor a method which provides 90 mol% or more conversion into the single form of trihydrate and does not teach employing a moistened gas in the preparation of hydrates. As such, the combination of Niewöhner and Bischoff does not teach each and every step of the presently claimed process."

These arguments have been considered and were deemed persuasive. Accordingly, the 35 U.S.C. §103(a) rejection of claims 1-5, 7 and 11-15 over Niewöhner *et al.* in view of Bischoff *et al.* (WO 01/19357) has been withdrawn.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

--No claims are allowed at this time.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday-Friday during regular business hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax, can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Humera N. Sheikh/
Primary Examiner, Art Unit 1615

hns

May 7, 2010